

# **NOTICE PROGRAM**

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION,

CASE NO. MDL NO. 1456 (CA:01-CV-12257-PBS) (D.MASS.)

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# FIRM OVERVIEW

Kinsella/Novak Communications ("KNC") provides nationally recognized expertise in the design of media-based legal notification programs for class actions and bankruptcies.

The firm has designed, implemented or consulted on over 250 class actions and bankruptcies and specializes in the most complex and often precedent-setting notice efforts. National and statewide notification programs include asbestos, breast implants, consumer fraud, home siding products, infant formula, polybutylene plumbing, tobacco, antitrust securities and Holocaust claims. The firm has selected and placed over \$135 million in paid legal advertising.

KNC develops advertisements, press materials, Web sites, and other notice materials bridging the gap between litigation complexities and the need for a clear and simple explanation of legal rights. In addition to designing and producing notices in "plain language", all KNC notice programs are fully compliant with Rule 23 of the Federal Rules of Civil Procedure and comparable state guidelines. The firm employs industry-recognized tools of media measurement to quantify the adequacy of the notice for the court.

# RELEVANT CASE EXPERIENCE

KNC has significant notification experience including consumer class actions involving pharmaceuticals.

#### PHARMACEUTICAL CASES

- > State of Connecticut v. Mylan Laboratories, Inc., MDL 1290, Misc. No. 99-276 (TFH-JMF) (Lorazepam and Clorazepate)
- ➤ In re Buspirone Antitrust Litigation, MDL-1413 (S.D.N.Y.) (BuSpar)
- ➤ In re Cardizem CD Antitrust Litigation, 99-MD-1278 (E.D. Mich.) (Cardizem)
- > State of Ohio v. Bristol-Myers Squibb, Co., 1:02-cv-01080 (D.D.C.) (Taxol)

#### OTHER SELECTED CASES

- ➤ In re Nasdaq Market-Makers Antitrust Litigation, No. M21-68 (RWS), 94 Civ. 3996 (RWS), MDL No. 1203 (S.D.N.Y.) (securities)
- ➤ In re Compact Disc Minimum Advertised Price Antitrust Litigation, MDL No. 1361 (D. Me.) (prerecorded music products)
- In re Toys "R" Us Antitrust Litigation, MDL No. 1211, Master File No. CV-97-5750 (E.D.N.Y.) (toys and other products)
- > Cox v. Shell Oil Co., No. 199,844 (Tenn. Ch. Ct., Obion County) (polybutylene pipe)
- Naef v. Masonite, No. CV-94-4033 (Ala. Cir. Ct., Mobile County) (hardboard siding)
- ➤ In re Holocaust Victims Assets Litigation, No. CV 96-4849 (Consolidated with CV-5161 and CV 97461) (E.D.N.Y.)
- > Ruff, et al. v. Parex, Inc., No. 96-CVS-0059 (N.C. Super. Ct., New Hanover County) (EIFS stucco)
- > Fettke v. McDonald's Corporation, Case No. 044109 (Cal. Super. Ct., Marin County) (trans-fatty acids)

# TECHNICAL APPROACH

KNC's technical approach is based on its expertise as a leading provider of notice in class actions, knowledge of court-approved notice programs at the state and federal levels and years of experience in designing and implementing legal notification programs both nationally and internationally.

KNC begins by conducting detailed research on the claim that is the subject of the class action and how it is related to a population, its location and temporal characteristics. This information identifies the demographic characteristics of class members — such as age, gender, income, and education level — and the geographic distribution of potential class members. This research provides the parameters for identifying and locating class members and shapes the scope of the notice program.

#### Specifically, KNC:

- Reviews demographic and product information provided by the client or independently researched and establishes a demographic profile of the target audience. All media selections are based on this profile in order to ensure the highest reach of potential class members and frequency of message exposure.
- ➤ Evaluates the effectiveness of media vehicles -- consumer magazines, newspapers, specialty publications, broadcast television, radio and the Internet -- in reaching the target audience.
- Analyzes publications using syndicated data sources and tools, such as the Audit Bureau of Circulation (ABC) statements, which certify how many readers buy or obtain copies of publications, and MediaMark Research ("MRI") which measures how many people open or read publications.
- Examines the geographic distribution of potential class members at the level of detail necessary to determine effective geographic coverage.
- > Selects media available during the established notice period ensuring timely notice to class members.
- ➤ Creates and implements all notice communications, including: published notice, print, audio and video news releases, television and radio spots, Internet advertising and Web sites.
- Ensures that published notices and long form notices are written in "plain language."

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- ➤ Uses established advertising relationships to negotiate the deepest available discounts on national advertising and secure optimum placement with respect to the media habits of the target audience.
- ➤ Designs and implements an "earned media" program to further supplement the published notice through print, audio and video news releases and non-paid media outreach. Tracks and verifies all media placements and press stories developed through "earned media."
- ➤ Designs and maintains a Web site to enable class members to access all relevant information including long form notices, claim forms and court documents. Provides registration and email capabilities on the site.
- ➤ Integrates all aspects of the notification program with selected claims administrators.
- ➤ Provides advice, affidavits, depositions and court testimony with respect to the design and implementation of the notification program.

# SITUATION ANALYSIS

The average wholesale price ("AWP") is the published price used to establish reimbursement rates for drugs industry-wide. Plaintiffs claim that the Defendants control the AWP for their drugs. Specifically, they claim that forty-two drug manufacturers artificially raised and falsely overstated the AWP of over 300 drugs. This resulted in inflated payments by consumers and other entities such as health and welfare plans and health insurers. Defendants deny these allegations.

The Court will conduct a two-phase trial beginning with four of the drug manufacturers. These companies (the "Defendants") are:

#### **AstraZeneca**

AstraZeneca PLC, Zeneca, Inc. AstraZeneca Pharmaceuticals L.P. AstraZeneca U.S.

#### The BMS Group

Bristol-Myers Squibb Co. Oncology Therapeutics Network Corp. Apothecon, Inc.

#### The Johnson & Johnson Group

Johnson & Johnson Centocor, Inc. Ortho Biotech McNeil-PPC, Inc. Janssen Pharmaceutica Products, L.P.

#### The Schering Plough Group

Schering-Plough Corporation Warrick Pharmaceuticals Corporation

Plaintiffs seek monetary compensation and a court order prohibiting the Defendants from inflating the AWP for their drugs.

# **CLASS DEFINITION**

The Classes includes the following:

#### Class 1: Medicare Part B Co-Payment Class

All natural persons nationwide who made, or who incurred an obligation enforceable at the time of judgment to make, a co-payment based on AWP for a Medicare Part B covered Subject Drug that was manufactured by AstraZeneca (AstraZeneca, PLC, Zeneca, Incl., AstraZeneca Pharmaceuticals L.P., and AstraZeneca U.S.), the BMS Group (Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.), or the Johnson & Johnson Group (Johnson & Johnson, Centocor, Inc., Ortho Biotech, McNeil-PPC, Inc., and Janssen Pharmaceutica Products, L.P.). The states excluded from this Class are: Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana and Virginia

#### Class 2: Third Party Payor MediGap Supplemental Insurance Class

All Third Party Payors who made reimbursements for drugs purchased in Massachusetts, or who made reimbursements for drugs and have their principal place of business in Massachusetts, based on AWP for a Medicare Part B covered Subject Drug that was manufactured by AstraZeneca (AstraZeneca, PLC, Zeneca, Incl., AstraZeneca Pharmaceuticals L.P., and AstraZeneca U.S.), the BMS Group (Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.), the Johnson & Johnson Group (Johnson & Johnson, Centocor, Inc., Ortho Biotech, McNeil-PPC, Inc., and Janssen Pharmaceutica Products, L.P.), or the Schering Plough Group (Schering-Plough Corporation and Warrick Pharmaceuticals Corporation).

# Class 3: Consumer and Third Party Payor Class for Medicare Part B Drugs Outside of the Medicare Context, i.e., Medicare Part B Drugs Paid for by Contract

All natural persons who made or who incurred an obligation enforceable at the time of judgment to make a payment for purchases in Massachusetts, all Third Party Payors who made reimbursements based on contracts expressly using AWP as a pricing standard for purchases in Massachusetts, and all Third Party Payors who made reimbursements based on contracts expressly using AWP as a pricing standard and have their principal place of business in Massachusetts, for a physician-administered Subject Drug that was manufactured by AstraZeneca (AstraZeneca, PLC, Zeneca, Incl., AstraZeneca Pharmaceuticals L.P., and AstraZeneca U.S.), the BMS Group (Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.), the Johnson & Johnson Group (Johnson & Johnson, Centocor, Inc., Ortho Biotech, McNeil-PPC, Inc., and Janssen Pharmaceutica Products, L.P.), or the Schering Plough Group (Schering-Plough Corporation and Warrick Pharmaceuticals Corporation). Included within this Class are natural persons who paid coinsurance (i.e., co-payments

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proportional to the reimbursed amount) for a Subject Drug purchased in Massachusetts, where such coinsurance was based upon use of AWP as a pricing standard. Excluded from this Class are any payments or reimbursements for generic drugs that are based on MAC and not AWP.

# PRODUCT BACKGROUND

The first phase of the lawsuit involves the four drug manufacturers and 15 drugs that are used to treat a wide range of medical conditions and diseases. The drugs are used in the treatment of, among others: anemia, arthritis, asthma, blood clots, cancer of the cervix and uterus, heart failure, HIV, Leukemia, lung and testicular cancer, ovarian and stomach cancer, prostate and breast cancer, and shingles. Exhibit 1 lists the drugs by primary and secondary indicators, manufacturers and dosages.

The specific drugs are:

#### **AstraZeneca**

Zoladex

#### **BMS Group**

Blenoxane Rubex Cytoxan Taxol Etopophos VePesid

Paraplatin

# Johnson & Johnson Group

Procrit Remicade

# **Schering-Plough Group**

Albuterol Proventil Intron A Temodar

Perphenazine

# NOTICE PLAN OVERVIEW

This plan is submitted by KNC in connection with *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, M.D.L. No. 1456 (CA: 01-CV-12257-PBS) in the District Court of Massachusetts. The plan outlines procedures to provide notice of the certification of this case as a class action consistent with the requirements set forth in Rule 23 of the Federal Rules of Civil Procedure. The Notice Program is directed to all members of the three certified Classes, except the Consumer Class Members in Class 3.

Based upon information provided by Counsel, the results of research on Class Members and their response to media and the media habits of the target audiences, the following four-part notice program is recommended:

- > Direct notice by first-class mail to:
  - All Third Party Payors ("TPP") whose names and addresses are readily identifiable.
  - Medicare Part B Beneficiaries who purchased the Covered Drugs during the Class Period, identified and provided by the Centers for Medicare and Medicaid Services ("CMS").
  - All callers to the toll-free information line who request a *Notice of Class Action Pendency* as a result of seeing the Publication Notice.
- ➤ Broad published notice through the use of paid media, including consumer magazines and newspaper supplements. Trade publications will be used to supplement the direct notice to TPPs.
- Earned media notice through a press release sent to major national print and electronic outlets and third-party organizations.
- Electronic notice through a dedicated Web site.

The Notice Program calls for different long form and publication notices tailored to either the TPPs or Medicare Part B Beneficiaries. The *Notice of Class Action Pendency* designed specifically for TPPs will be sent to them ("TPP *Notice of Class Action Pendency*"). The *Notice of Class Action Pendency* designed specifically for Medicare Part B Beneficiaries will be directed to them ("Medicare *Notice of Class Action Pendency*"). The Publication Notices will be similarly tailored.

# DIRECT NOTICE

#### THIRD PARTY PAYORS

Direct mail notice to TPPs will consist of mailing the TPP *Notice of Class Action Pendency* (Exhibit 2) to appropriate identifiable Class Members informing them of their legal rights and how they may participate in or opt-out of the class action. The TPP *Notice of Class Action Pendency* will be sent to:

- ➤ Appropriate entities likely to be Class Members, in the proprietary TPP Database compiled by Complete Claim Solutions ("CCS"), the class administrator. The Database includes insurance companies, healthcare and welfare funds, employee benefit funds, third-party administrators, pharmacy benefit managers and other record keepers for noticing purposes in TPP class actions. The Database was compiled from contacting, researching and accessing the records of various databases and listings of affiliations, group insurance plans, self-insureds, ERISA funds, pharmacy benefit manager listings, etc. as follows:
  - Pharmacy Benefit Management Institute;
  - Benefits SourceBook;
  - Managed Care Information Centers;
  - Judy Diamond Associates;
  - AM Best Company;
  - Association of Managed Care Providers;
  - Society of Professional Benefit Administrators;
  - American's Health Insurance Plans;
  - Self-Insurance Institute of America; and
  - National Association of Insurance Commissioners.

#### Included in the Database are:

- Approximately 29,000 companies with 100 or more employees that have self-funded (fully or partially) plans, derived from Form 5500 filings;
- 1,356 Third-Party Claim Administrators; and
- 1,300 member companies of American Health Insurance Plans that provide or administer health insurance benefits to over 200 million Americans which represent 90 percent of the managed care market (HMOs, PPOs and POSs, etc.).

The Database is regularly updated with new entries from the above sources as well as TPPs identified through other class action litigations.

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#### MEDICARE PART B BENEFICIARIES

The Court has subpoenaed the names and addresses of all Medicare Part B Beneficiaires who purchased the Covered Drugs during the Class Period, from CMS. All identifiable Medicare Part B Beneficiaries will be mailed the Medicare *Notice of Class Action Pendency* (Exhibit 2). Mail will be address corrected if returned and re-mailed, if possible.

#### CALLERS TO THE TOLL-FREE NUMBER

All callers to a toll-free information line who request the either the TPP *Notice of Class Action Pendency* or the Medicare *Notice of Class Action Pendency* will be mailed the requested Notice. A toll-free number for this information line will prominently appear in the Publication Notice. Class Members may also download either Long Form Notice, in PDF format, from the Notice Web site.

# PAID MEDIA METHODOLOGY

KNC notice plans directed to unidentified class members (1) identify the demographics of class members and establish a target audience; (2) outline the methodology for selecting the media and other plan elements and how they relate to product usage or exposure; and (3) provide results that quantify for the court the adequacy of the notice based upon recognized tools of media measurement.

In the wake of the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), and *Kumho Tire Company v. Carmichael*, 526 U.S. 137 (1999), the reliability of a notice expert's testimony should be tested against the standards developed within the media industry for determining whether, to what degree and at what frequency a target audience has been reached. In assessing the expert's reliability, the court must determine whether the testifying expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," (526 U.S. at 152). That showing would likely require evidence that the expert's data and methodology are similar to that used by professionals in the relevant field.

In keeping with the *Daubert* and *Kumho* rulings, KNC employs the methodology and measurement tools used in the media planning and advertising industry for designing and measuring the adequacy of a paid media program to reach a particular audience.

Choosing a target audience encompassing the characteristics of Class Members is the first step in designing the paid media program. Media vehicles are chosen based on their ability to provide effective and cost efficient reach among the target audience. The selected media vehicles are then measured against the target audience to establish the *reach* of the media program and the *frequency* of exposure to the media vehicles. *Reach* and *frequency* estimates are two of the primary measurements used to quantify the media penetration of a target audience.

- > Reach is the estimated percentage of a target audience reached one or more times through a specific media vehicle or combination of media vehicles within a given period.
- > Frequency is the estimated average number of times an audience is exposed to an advertising vehicle carrying the message within a given period of time.

# **TARGET AUDIENCES**

To develop a profile of the demographics and media habits of Medicare Part B Beneficiary Class Members and their heirs, KNC analyzed syndicated data available from the 2005 Doublebase Survey<sup>1</sup> from MediaMark Research, Inc. ("MRI").

MRI is the leading U.S. supplier of multimedia audience research. As a nationally accredited research firm, it provides information to magazines, television, radio, Internet and other media, leading national advertisers and over 450 advertising agencies – including 90 of the top 100 in the United States. MRI's nationally syndicated data are widely used by these companies as the basis for the majority of the media and marketing plans written for advertised brands in the United States.

Specifically, MRI provides data on audience size, composition and other relevant factors pertaining to major media vehicles. MRI presents a single-source measurement of major media, products, services and in-depth consumer demographic and lifestyle characteristics.

Using MRI data, KNC selected two demographics that encompass Medicare Part B Beneficiary Class Members:

- ➤ Individuals with medical insurance through Medicare ("Medicare Beneficiaries").
- ➤ Adults 18 years of age and older ("Adults 18+"), which encompasses any heirs of Medicare Beneficiaries.

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<sup>&</sup>lt;sup>1</sup> The study, conducted since 1979, surveys persons 18 years of age and older in the contiguous 48 states. MRI conducts more than 26,000 personal interviews with consumers in two waves annually each lasting six months and consisting of 13,000 interviews. Produced annually by MRI, the Doublebase study consists of two full years of data drawn from over 50,000 respondents. Consumer information is recorded on 500 product/service categories, 6,000 brands and various lifestyle activities. Respondents are selected based on the ability to project their responses nationally.

## **DEMOGRAPHICS**

The chart below outlines the overall demographics of the two target audiences:

DEMOGRAPHICS	MEDICARE BENEFICIARIES	ADULTS 18+
Male	42.8%	48.0%
Female	57.2%	52.0%
Age		
18 - 24	2.9%	13.0%
25 - 34	3.4%	18.4%
35 - 44	3.9%	20.7%
45 - 54	6.6%	19.0%
55 - 64	10.8%	12.8%
65+	72.4%	16.1%
Education		
Graduated/Attended College	35.9%	51.9%
Graduated High School	38.7%	31.8%
Household Income		
Under \$10,000	10.2%	6.2%
\$10,000 - \$29,999	42.0%	21.7%
\$30,000 - \$49,999	23.9%	20.9%
\$50,000 - \$74,999	13.9%	20.2%
\$75,000 - \$99,999	5.4%	13.1%
\$100,000+	4.7%	18.1%
Ethnicity		
Caucasian	84.0%	77.9%
African-American	11.0%	11.4%
Hispanic	5.7%	12.2%
Asian	1.2%	2.5%
Location <sup>2</sup>		
A & B Counties	61.4%	71.1%
C & D Counties	38.6%	28.9%

<sup>&</sup>lt;sup>2</sup> A Counties, as defined by A.C. Nielsen Company, are all counties belonging to the 25 largest metropolitan areas. These metro areas correspond to the MSA (Metropolitan Statistical Area) and include the largest cities and consolidated areas in the United States. B Counties, as defined by A.C. Nielsen Company, are all counties not included under A that are either over 150,000 population or in a metro area over 150,000 population according to the latest census. C Counties, as defined by A.C. Nielsen Company, are all counties not included under A or B that either have over 40,000 population or are in a metropolitan area of over 40,000 population according to the late census. D Counties are, essentially, rural counties in the Nielsen classification system of A, B, C, D counties.